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REMARKS/ARGUMENTS

Reexamination and reconsideration of this Application, withdrawal of the rejection, and formal notification of the allowability of all claims as now presented are earnestly solicited in light of the above amendments and remarks that follow.

I. Amendments to the Claims

Claims 1-20 and 27-30 are pending in the application. Claims 2 and 17 have been amended to correct a minor typographical error with respect to the Markush claim language. Claim 16 has been amended to incorporate the subject matter of original Claims 25 and 26. Claim 29 has been amended to retain consistency with amended Claim 16. Claims 21-26 and 31-50 have been cancelled without prejudice or disclaimer. Applicants respectfully submit that no new matter has been introduced by these amendments. None of the amendments should be considered acquiescence to any claim rejection of record.

II. Objection to the Specification

The Examiner has objected to designation of the present application as a continuation in "Cross Reference to Related Applications" section of the patent application. As requested by the Examiner, Applicants have amended the specification to refer to the present application as a divisional. Additionally, the cross reference paragraph has been amended to insert the issued patent number for the parent application. As a result, Applicants respectfully request reconsideration and withdrawal of this objection.

III. Rejections Under 35 U.S.C. §112

Claims 2 and 17 stand rejected under 35 U.S.C. §112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that Applicants regard as the invention. Specifically, the Examiner has objected to the wording of the Markush group introductory phrase. In response, Applicants have amended Claims 2 and 17 in a non-limiting manner to recite "from the group consisting of" as requested by the Examiner. In

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light of the foregoing, Applicants respectfully request reconsideration and withdrawal of this rejection.

IV. Applicants' Claimed Invention

The present invention is directed to a polymer composition comprising a desired monofunctional polymer and a dialkoxy- or diaryloxy-terminated polymer. The dialkoxy- or diaryloxy-terminated polymer results from treating the polymer composition with, for example, an alkylating agent. As explained in the specification, this treatment step can negate the need for removal of a diol contaminant using laborious chromatography techniques. By reacting the -OH groups of the diol to form relatively inert alkoxy or aryloxy groups, the resulting polymer composition can be further reacted to form a highly activated monofunctional polymer reagent without also creating an activated difunctional polymer component that can lead to undesirable crosslinking when the polymer composition is reacted with a biologically active agent. Thus, as recited in Claim 1, the present invention is directed to a polymer composition comprising a mixture of a desired monofunctional polymer derivative having the structure R-O-POLY-R' and a polymer having the relatively inert structure R-O-POLY-O-R, wherein POLY is a water soluble and non peptidic polymer, such as PEG, R is an alkyl or an aryl group, and R' is a functional group. Similarly, in Claim 16, the monofunctional polymer derivative is claimed in the absence of the polymer diol (HO-POLY-OH).

V. Rejections Under 35 U.S.C. §102

Claims 16-20 and 22 stand rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,252,714 to Harris *et al.* In order to expedite the prosecution, Applicants have amended Claim 16 in order to incorporate the subject matter of original Claims 25 and 26, neither of which are mentioned in the present rejection. The Harris reference does not teach or suggest a polymer composition absent HO-POLY-OH. In fact, the Harris reference is silent as the level of diol contamination of the functionalized reagents described therein. Further, the Harris reference does not teach a polymer of the structure R-O-POLY-R', wherein R is alkyl or aryl, R' is -O-(CH₂)_n-CHO or O-(CH₂)_n-CH(ZR₅)₂ wherein n is 1-6, Z is O or S, and R₅ is H or

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an alkyl group. Since the Harris reference clearly fails to teach or suggest the subject matter of amended Claims 16, or any claim dependent thereon, Applicants respectfully request reconsideration and withdrawal of this rejection.

Claims 1-9, 11, 14-24, 26, 29, and 30 stand rejected under 35 U.S.C. §102(b) as being anticipated by either U.S. Patent No. 5,298,410 to Phillips *et al.* or U.S. Patent No. 5,532,154 to Snow *et al.* Applicants respectfully traverse these rejections.

The Snow and Phillips references are directed to low diol polyalkylene oxide-containing compositions useful for covalently attaching to biologically active proteinaceous substances. Both references suggest the use of a "low diol" polyalkylene oxide reagent. The cited references suggest either purchasing a low diol PEG reagent available from Union Carbide Corporation, or forming a purified monofunctional PEG reagent by separating the undesired difunctional polymers using either ionic exchange chromatography to separate difunctional succinate esters of PEG or reverse phase thin layer chromatography to separate difunctional dimethoxytrityl (DMT) ethers of PEG (See '150 patent, column 13, line 58 - column 15, line 34). However, none of the methods for forming low diol PEG reagents suggested in the Snow and Phillips references involve formation of the polymer mixture recited in Claim 1 of the present invention. Specifically, there is no teaching in either reference to form a polymer having the structure R-O-POLY-O-R, wherein R is an alkyl or aryl group. Instead, the two references teach conventional purification methods that involve reacting the original PEG reagent mixture (i.e., mixture of mPEG and PEG diol) to form a functionalized mixture of polymers that is then separated by either ionic exchange chromatography (e.g., succinate ester terminated polymer mixture) or reverse phase thin layer chromatography (e.g., DMT terminated polymer mixture). There are no reaction steps described in either patent that lead to the formation of the dialkoxy- or diaryloxy-terminated polymer claimed in the present application. In sum, neither reference teaches polymer compositions of the type presently claimed, i.e., low diol content polymer compositions containing diaryloxy or dialkoxy-terminated polymer. As a result, Applicants respectfully request reconsideration and withdrawal of this rejection as applied to Claim 1 and all claims dependent thereon.

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With respect to Claim 16 and all claims dependent thereon, Applicants respectfully submit that the subject matter of amended Claim 16 is also not taught by the Snow and Phillips references. As amended, Claim 16 recites that the R' functional group is either an aldehyde, aldehyde hydrate or acetal having a structure as originally presented in Claims 25 and 26. Neither reference teaches such polymer structures or the use of such functional groups. Instead, both references are directed to the formation of mPEG succinate and mPEG N-succinimidyl succinate. As a result, Applicants respectfully request reconsideration and withdrawal of this rejection as applied to Claims 16 and all claims dependent thereon.

VI. Obviousness-Type Double Patenting Rejections

Claims 1-6, 8, 9, 11, 16-21, 23, 24, and 26 stand rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over Claims 1-21 of U.S. Patent No. 6,362,254. In addition, Claims 1-8, 10-23, and 25-30 stand rejected under unobviousness-type double patenting as being unpatentable over Claims 1-29 of U.S. Patent 6,495,659. The Office Action does not include any explanation regarding the reasoning behind these rejections. Applicants respectfully traverse these rejections.

As stated in the Manual of Patent Examining Procedure (M.P.E.P.), [o]bviousness-type double patenting requires rejection of an application claim when the claimed subject matter is **not patentably distinct** from the subject matter claimed in a commonly owned patent when the issuance of a second patent would provide unjustified extension of the term of the right to exclude granted by a patent. See *Eli Lilly & Co. v. Barr Labs., Inc.*, 251 F.3d 955, 58 USPQ2d 1865 (Fed. Cir. 2001); *Ex parte Davis*, 56 USPQ2d 1434, 1435-36 (Bd. Pat. App. & Inter. 2000). See M.P.E.P. Section 804, Paragraph 8.32. (Emphasis in original).

Moreover, this section of the M.P.E.P. sets forth that [a] double patenting rejection of the obviousness-type is "analogous to [a failure to meet] the nonobviousness requirement of 35 U.S.C. 103 except that the patent principally underlying the double patenting rejection is not considered prior art. *In re Braithwaite*, 379 F.2d 594, 154 USPQ 29 (CCPA 1967). Therefore, any analysis employed in an obviousness-type double patenting rejection parallels the guidelines

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for analysis of a 35 U.S.C. 103 obviousness determination. *In re Braat*, 937 F.2d 589, 19 USPQ2d 1289 (Fed. Cir. 1991); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

As noted above, pending independent Claim 1 is directed to a polymer composition comprising a mixture of a polymer having the structure R-O-POLY-R' and a polymer having the structure R-O-POLY-O-R, wherein POLY is a water soluble and non-peptidic polymer, R is an alkyl and aryl group, and R' is a functional group. Thus, independent Claim 1 is directed to a mixture of a monofunctional polymer derivative, such as a mPEG derivative, and a dialkoxy- or a diaryloxy-terminated polymer, such as dimethoxy PEG. Similarly, Claim 16 is directed to a monofunctional polymer having the structure given above in the absence of a polymeric diol, wherein the R' functional group is an aldehyde, aldehyde hydrate, or an acetal having a given structure.

In contrast, the '254 patent claims an activated water soluble polymer comprising a PEG backbone having at least one terminus bonded to a forked structure that includes two reactive groups. There is absolutely no description in the claims of the '254 patent of the absence of polymeric diol or the presence of a dialkoxy- or diaryloxy-terminated polymer.

The '659 patent is similarly irrelevant to the claims of the present invention. The claims of the '659 patent are directed to a sterically hindered polymer comprising a polymer backbone attached to an alkanoic acid derivative of defined structure, the alkanoic acid moiety including an alkyl or aryl group attached to the carbon atom adjacent to the carbonyl group. There is nothing in the claims of the '659 patent to suggest a polymer composition that is absent a polymeric diol or that includes a dialkoxy- or a diaryloxy-terminated polymer as recited in Applicants' pending claims.

There is simply nothing remotely suggestive of the structure R-O-POLY-O-R in any of the claims of the cited patents. Further, there is nothing in the claims of the cited patents to suggest formation of a polymer mixture absent a polymer diol. Since the claims of the cited patents clearly fail to teach or suggest one or more of the elements of each of the pending claims, the pending claims cannot be considered obvious in light of the claims of the cited patents and Applicants respectfully request reconsideration and withdrawal of these rejections.

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It is believed that all pending claims are now in condition for immediate allowance. It is requested that the Examiner telephone the undersigned should the Examiner have any comments or suggestions in order to expedite examination of this case.

It is not believed that extensions of time or fees for net addition of claims are required, beyond those that may otherwise be provided for in documents accompanying this paper. However, in the event that additional extensions of time are necessary to allow consideration of this paper, such extensions are hereby petitioned under 37 CFR § 1.136(a), and any fee required therefore (including fees for net addition of claims) is hereby authorized to be charged to Deposit Account No. 16-0605.

Respectfully submitted,



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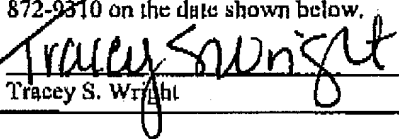
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